



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10717]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number \_\_\_\_\_

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).
3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

*Contents*

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10717 Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness  
Monitoring Project (TMP) Protocols

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

*Information Collection*

1. *Type of Information Collection Request:* New Collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols; *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR Parts 422 and 423, Medicare Part D plan sponsors and Medicare Advantage organizations are required to comply with all Medicare Parts C and D program requirements. CMS' annual audit plan ensures that we evaluate sponsoring organizations' compliance with these requirements by conducting program audits that focus on high-risk areas that have the greatest potential for beneficiary harm. As such, CMS has developed the following audit protocols for use by sponsoring organizations to prepare for their audit:

- Compliance Program Effectiveness (CPE)

- Part D Formulary and Benefit Administration (FA)
- Part D Coverage Determinations, Appeals, and Grievances (CDAG)
- Part C Organization Determinations, Appeals, and Grievances (ODAG)
- Special Needs Plans Care Coordination (SNPCC)

CMS generally conducts program audits at the parent organization level in an effort to reduce burden and, for routine audits, subjects each sponsoring organization to all applicable program area protocols. For example, if a sponsoring organization does not offer a special needs plan, or an accrediting organization has deemed a special needs plan compliant with CMS regulations and standards, CMS would not apply the SNPCC protocol. Likewise, CMS would not apply the ODAG audit protocol to an organization that offers only a standalone prescription drug plan since that organization does not offer the MA benefit. Conversely, ad hoc audits resulting from referral may be limited in scope and, therefore, all program area protocols may not be applied.

In addition, as part of the robust program audit process, CMS also requires sponsoring organizations that have undergone a program audit and found to have deficiencies to undergo a validation audit to ensure correction. The validation audit uses the same audit protocols, but only tests the elements where deficiencies were found as opposed to re-administering the entire audit. Finally, CMS conducts annual industry-wide timeliness monitoring of all Part C organizations by using a subset of the ODAG protocol. However, sponsoring organizations that successfully submitted all of their Part C data in response to a program audit in the prior year are excluded from submitting new data for the timeliness monitoring effort in the year following their program audit.

The information gathered during this program audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM) and CMS Regional Offices to assess sponsoring organizations' compliance with Medicare program

requirements. If outliers or other data anomalies are detected, Regional Offices will work in collaboration with MOEG and other divisions within CMS for follow-up and resolution.

Additionally, MA and Part D organizations will receive the audit results and will be required to implement corrective action to correct any identified deficiencies. *Form Number:* CMS-10717 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 190; *Total Annual Responses:* 179; *Total Annual Hours:* 36,082. (For policy questions regarding this collection contact Kellie Simons at 410-786-0886.)

**Dated:** December 3, 2019.

**William N. Parham, III,**

*Director,*

*Paperwork Reduction Staff,*

*Office of Strategic Operations and Regulatory Affairs.*

**4120-01-U-P**

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